UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2277-3
Program	Prior Authorization/Medical Necessity
Medication	Pyrukynd® (mitapivat)
P&T Approval Date	5/2022, 5/2023, 5/2024
Effective Date	8/1/2024

1. Background:

Pyrukynd® (mitapivat) is a pyruvate kinase activator indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Pyrukynd** will be approved based on **all** of the following criteria:

   a. Diagnosis of pyruvate kinase (PK) deficiency based on **all** of the following:

      (1) Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 is a missense variant

      -AND-

      (2) Patient is not homozygous for the c.1436G>A (p.R479H) variant

      -AND-

      (3) Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene

      -AND-

   b. Used for the treatment of hemolytic anemia

      -AND-

   c. **One** of the following:

      (1) **Both** of the following:

         i. Baseline hemoglobin less than or equal to 10 g/dL

         -AND-

         ii. Patient has had no more than 4 transfusions in the previous 52 weeks and no transfusions in the preceding 3-month period

-OR-

(2) Patient has had a minimum of 6 transfusion episodes in the preceding 52 weeks

-AND-

d. Prescribed by a nephrologist or hematologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Pyrukynd** will be approved based on **one** of the following criteria:

(1) **Both** of the following:

i. Documentation of positive clinical response to Pyrukynd therapy

-AND-

ii. Prescribed by, or in consultation with, a nephrologist or hematologist

Authorization will be issued for 12 months.

-OR-

(2) Documentation does not provide evidence of positive clinical response to Pyrukynd therapy, allow for dose titration with discontinuation of therapy

Authorization will be issued for 4 weeks.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Pyrukynd [package insert]. Cambridge, MA: Agios Pharmaceuticals, Inc.; February 2022.

Program	Prior Authorization/Medical Necessity – Pyrukynd® (mitapivat)
Change Control	
5/2022	New program.
5/2023	Annual review. No changes.
5/2024	Updated initial approval duration from 6 months to 12 months. Simplified reauthorization criteria.